REMARKS

The applicants have studied the Office Action dated February 26, 2004, and have made amendments to the claims. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claims 84-88 and 91-106 are pending, claims 56-83, 89 and 90 have been canceled without prejudice or disclaimer; claims 84, 91, 92, and 95 has been amended, and new claims 96-106 have been added. Reconsideration and allowance of all the pending claims in view of the above amendments and the following remarks are respectfully requested.

The applicants wish to thank the Examiner for the time in the April 30, 2004 interview with the applicant's representative. The discussions were helpful and are believed to have moved this case towards allowance, as discussed below.

Claims 84-95 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. The applicants have reviewed the language pointed out by the Examiner in claim 84 and have amended the claim to make it clear that claim recites a method practiced in an external infusion device. Therefore, it is respectfully submitted that the rejection of claims 56-115 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

Claims 84, 86-88 and 92-95 were rejected under 35 U.S.C. § 102(b) as being anticipated by Worthington et al. This rejection is respectfully traversed.

In view of the amendments made above that clearly define claims 84, 86-88 and 92-95 as methods for use in an external infusion device, and the discussions in the interview, it is respectfully submitted that the claims are patentably distinguished over the Worthington et al. reference for the reasons previously raised in the prior response to the February 28, 2003 Office Action. In addition, the Examiner's comments where she states the "claims as written" are anticipated by Worthington et al. reference is incorrect. The Examiner has misstated the language in claim 84. Claim 84 recites "calculating an estimate of the bolus amount of insulin to

be infused into the body based upon the externally supplied values and the estimate of the carbohydrate to be ingested by the body" (emphasis added), which is the opposite of Worthington et al. reference where it recommends the amount of carbohydrate to take to reach a desired insulin or glucose level.

Applicants for clarity, also note the Examiner in the October 8, 2003 Restriction correctly stated that these claims do not require an indication device, and are now allowable, since the claims recite a method practiced in the external infusion device to provide an estimate of the amount of insulin to be infused based upon the externally supplied values and the estimate of the carbohydrate to be ingested by the body that may be used by the user in the external infusion device, as recited in the claims.

To further advance the prosecution of the application, claims 89 and 90 have been canceled. Claim 90 was not shown as rejected. The limitations of claim 90 have been incorporated into claim 84. Claims 91, 92 and 95 have been amended to make the language consistent with the amended language of claim 84. No new matter has been added.

Therefore, it is respectfully submitted that the rejection of claims 84, 86-88 and 92-95 under 35 U.S.C. § 102(b) should be withdrawn.

Claims 84, 86-88 and 91-95 were rejected under 35 U.S.C. § 102(b) as being anticipated by Franetzki et al. This rejection is respectfully traversed.

In view of the amendments made above that clearly define claims 84, 86-88 and 91-95 as methods for use in an external infusion device, and the discussions in the interview, it is respectfully submitted that the claims are patentably distinguished over the Franetzki et al. reference for the same reasons as discussed in regards to the Worthington et al. reference. The Examiner cited Col. 3, lines 30-32, but these lines deal with infusing insulin and do not recite a bolus or carbohydrates. Also, Col. 5, lines 59-68 recite bread units (BE), but the Franetzki et al. reference does not make clear how the BE are used. Thus, the Franetzki et al. reference does not

disclose a method used in an external infusion device to provide an estimate of the amount of insulin to be infused based upon the externally supplied values and the estimate of the carbohydrate to be ingested by the body that may be used by the user in the external infusion device, as recited in the claims.

To further advance the prosecution of the application, claims 89 and 90 have been canceled. Claim 90 was not shown as rejected. The limitations of claim 90 have been incorporated into claim 84. Claims 91, 92 and 95 have been amended to make the language consistent with the amended language of claim 84. No new matter has been added.

Therefore, it is respectfully submitted that the rejection of claims 84, 86-88 and 92-95 under 35 U.S.C. § 102(b) should be withdrawn.

Claims 84, 86-88 and 91-95 were rejected under 35 U.S.C. § 102(b) as being anticipated by Aoki. This rejection is respectfully traversed.

In view of the amendments made above that clearly define claims 84, 86-88 and 91-95 as methods for use in an external infusion device, and the discussions in the interview, it is respectfully submitted that the claims are patentably distinguished over the Aoki reference for the same reasons as discussed in regards to the Worthington et al. reference. The Examiner cited Col. 5, lines 55-62 and Col. 6, lines 63-68, as showing an estimate of a bolus based on carbohydrates. but these lines deal with infusing insulin and do not recite a bolus or carbohydrates. However, like Worthington et al. reference, the Examiner has misstated the language in claim 84. Claim 84 recites "calculating an estimate of the bolus amount of insulin to be infused into the body based upon the externally supplied values and the estimate of the carbohydrate to be ingested by the body" (emphasis added), which is the opposite of in the Aoki reference where it recommends the amount of carbohydrate to take to reach a desired insulin or glucose level. Thus, the Aoki reference does not disclose a method used in an external infusion device to provide an estimate of the amount of insulin to be infused based upon the externally

supplied values and the estimate of the carbohydrate to be ingested by the body that may be used by the user in the external infusion device, as recited in the claims.

To further advance the prosecution of the application, claims 89 and 90 have been canceled. Claim 90 was not shown as rejected. The limitations of claim 90 have been incorporated into claim 84. Claims 91, 92 and 95 have been amended to make the language consistent with the amended language of claim 84. No new matter has been added.

Therefore, it is respectfully submitted that the rejection of claims 84, 86-88 and 92-95 under 35 U.S.C. § 102(b) should be withdrawn.

Claims 84, 86-88 and 91-95 were rejected under 35 U.S.C. § 102(b) as being anticipated by Tetzlaff et al. This rejection is respectfully traversed.

In view of the amendments made above that clearly define claims 84, 86-88 and 91-95 as methods for use in an external infusion device, and the discussions in the interview, it is respectfully submitted that the claims are patentably distinguished over the Tetzlaff et al. reference for the same reasons as discussed in regards to the Worthington et al. reference. The Tetzlaff et al. reference does not disclose a bolus estimator in an external infusion device. Rather, it is directed to a food library on a personal computer. The Examiner cited Col. 6, lines 59-63, but these lines merely deal with adding an entry to the food model. In addition, Col. 5, lines 15-24 recite rules that are applied if thresholds are exceeded, but no estimate is made. For instance, in the Tetzlaff et al. example at Col. 5, lines 16-24, it would not matter if 1 or 100 carbohydrates are over the ceiling. Only insulin + 10 would be taken and no estimate is made. Thus, the Tetzlaff et al. reference does not disclose a method used in an external infusion device to provide an estimate of the amount of insulin to be infused based upon the externally supplied values and the estimate of the carbohydrate to be ingested by the body that may be used by the user in the external infusion device, as recited in the claims.

To further advance the prosecution of the application, claims 89 and 90 have been canceled. Claim 90 was not shown as rejected. The limitations of claim 90 have been incorporated into claim 84. Claims 91, 92 and 95 have been amended to make the language consistent with the amended language of claim 84. No new matter has been added.

Therefore, it is respectfully submitted that the rejection of claims 84, 86-88 and 92-95 under 35 U.S.C. § 102(b) should be withdrawn.

Claim 85 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Worthington et al. in view of Welch et al. This rejection is respectfully traversed.

As discussed above, independent claim 84 was patentably distinguished over the Worthington et al. reference. Accordingly, dependent claim 85 is distinguished over the Worthington et al. reference for the same reasons.

The Welch et al. reference does not make up for the deficiencies of the Worthington et al. reference. As previously discussed in the response to the February 28, 2003 Office Action, the Welch et al. reference does not disclose, teach or suggest a method of estimating a bolus amount of insulin to be infused based upon an estimate of carbohydrate to be ingested by the body, as recited in the claims.

Therefore, it is respectfully submitted that the rejection of claim 85 under 35 U.S.C. § 103(a) should be withdrawn.

Claim 85 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Franetzki et al. in view of Welch et al. This rejection is respectfully traversed.

As discussed above, independent claim 84 was patentably distinguished over the Franetzki et al. reference. Accordingly, dependent claim 85 is distinguished over the Franetzki et al. reference for the same reasons.

The Welch et al. reference does not make up for the deficiencies of the Franetzki et al. reference. As previously discussed in the response to the February 28, 2003 Office Action, the Welch et al. reference does not disclose, teach or suggest a method of estimating a bolus amount of insulin to be infused based upon an estimate of carbohydrate to be ingested by the body, as recited in the claims.

Therefore, it is respectfully submitted that the rejection of claim 85 under 35 U.S.C. § 103(a) should be withdrawn.

Claim 85 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Aoki in view of Welch et al. This rejection is respectfully traversed.

As discussed above, independent claim 84 was patentably distinguished over the Aoki reference. Accordingly, dependent claim 85 is distinguished over the Aoki reference for the same reasons.

The Welch et al. reference does not make up for the deficiencies of the Aoki reference. As previously discussed in the response to the February 28, 2003 Office Action, the Welch et al. reference does not disclose, teach or suggest a method of estimating a bolus amount of insulin to be infused based upon an estimate of carbohydrate to be ingested by the body, as recited in the claims.

Therefore, it is respectfully submitted that the rejection of claim 85 under 35 U.S.C. § 103(a) should be withdrawn.

Claim 85 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Tetzlaff et al. in view of Welch et al. This rejection is respectfully traversed.

As discussed above, independent claim 84 was patentably distinguished over the Tetzlaff et al. reference. Accordingly, dependent claim 85 is distinguished over the Tetzlaff et al. reference for the same reasons.

The Welch et al. reference does not make up for the deficiencies of the Tetzlaff et al. reference. As previously discussed in the response to the February 28, 2003 Office Action, the Welch et al. reference does not disclose, teach or suggest a method of estimating a bolus amount of insulin to be infused based upon an estimate of carbohydrate to be ingested by the body, as recited in the claims.

Therefore, it is respectfully submitted that the rejection of claim 85 under 35 U.S.C. § 103(a) should be withdrawn.

Dependent claims 96-106 have been added to more fully define the applicants' embodiments of the invention and are patentably distinguished over the cited prior art for the same reasons as claim 84. Claims 96 and 97 recite that the externally supplied values are not limited to food codes or carbohydrate values, but can include other parameters, including but not limited to those recited in claims 96 and 97. Claim 98 recites that the externally supplied values may be stored in the memory of the external device and used either one time or multiple times. Claims 99-101 recite that the user can review the estimate, and then provide it to the processor of the external infusion device. Claim 100 recites that the estimate can be reviewed and adjusted, and claim 101 recites that the user provides the estimate to the processor of the external infusion device by using the at least one data input device. Thus, the user could for instance, but not limited to, enter the estimate with a single key stroke as is or reenter it all manually by keystrokes, and/or adjust the number before entering. Claims 102-106 are directed to the at least one data input device and how it interfaces with the at least one processor. No new matter has been added.

In view of the foregoing, it is respectfully submitted that the application and all the pending claims are in condition for allowance. Examination and consideration of the application, as amended, are requested.

If, for any reason, the Examiner finds that the application is other than in condition for allowance and believes that a telephone interview would advance the prosecution of the application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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